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MAY 21 2004

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Kacy Arnold
Regulatory Specialist

Proprietary Name: MicroMax® Suture Anchor

Common Name: Suture Anchor

Classification Name: Fastener, Fixation, Biodegradable soft tissue, 888.3045

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- LactoSorb® Soft Tissue Screw and Washer (K012572)

Device Description:

This device is a resorbable suture anchor designed to attach soft tissue to bone. The resorbable fixation anchor is comprised of L-Lactide / Glycolide material. The poly L-Lactic/polyglycolic acid copolymer degrades by hydrolysis into L-lactic and glycolic acids. These hydrolytic products are then further degraded into carbon dioxide and water via the cellular Krebs cycle. The material and manufacturing for this device is identical to the predicate device, LactoSorb® L15 Soft Tissue Screw and Washer, K012572.

The suture anchor measures 3.0mm in diameter and 9.0mm in length. It is a two-piece assembly, consisting of a body and a head portion. The body portion engages the bone, which is enhanced by means of seven circumferential ribs. The ribs measure 3.25mm in diameter. In addition, the body has two wings, that when deployed will flange outward into the bone. Upon deployment, the diameter at the flanged wings is 4mm.

The head portion provides a means to drive the anchor in as well as to attach suture to the anchor. The anchor has an eyelet through the head portion to allow suture to pass through which will be used to fasten the tissue to bone. The device will be pre-loaded with any legally marketed, size 2 suture.

Instrumentation is provided for proper use and placement of the device.

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P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639 ■ FAX 574.267.8137 ■ E-MAIL
biomet@biomet.com

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Intended Use:

The MicroMax™ Suture Anchor is intended for use in soft tissue reattachment procedures in the shoulder, wrist, elbow and knee. Specific indications are as follows:

Shoulder Indications:

- Bankart repair
- SLAP lesion repair
- Acromioclavicular (ACL) separation
- Rotator cuff repair
- Capsule repair or capsuloabral reconstruction
- Biceps tenodesis, deltoid repair

Wrist Indications:

- Scapholunate ligament reconstruction

Elbow Indications:

- Tennis elbow repair
- Ulnar or radial collateral ligament reconstruction
- Biceps tendon reattachment
- Medial and lateral repairs

Knee Indications (Extra-capsular repair):

- Medial collateral ligament repair
- Lateral collateral ligament repair
- Posterior oblique ligament repair
- Joint capsule closure
- Iliotibial band tenodesis reconstruction
- Patellar ligament/tendon repair
- Vastus medialis obliquus (VMO) muscle advancement

The device is pre-loaded with suture for use at the discretion of the physician.

Summary of Technologies: The MicroMax™ Suture Anchor technological characteristics (material and design) are similar to predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 1 2004

Ms. Kacy Arnold, RN, MBA
Regulatory Specialist
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581

Re: K040475
Trade/Device Name: MicroMax™ Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 23, 2004
Received: February 24, 2004

Dear Ms. Arnold:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040475

Device Name: MicroMax™ Suture Anchor

Indications For Use:

Indications for the MicroMax™ Suture Anchor include use in soft tissue reattachment procedures in the shoulder, wrist, elbow and knee. Specific indications are as follows:

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Mark N. Milhouse

(Division Sign-Off)
Division of General, Restorat
and Neurological Devices

510(k) Number K040475

Prescription Use __X__ AND/OR Over-The-Counter Use __no__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)